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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/813,323	03/10/97	BALTIMORE	D	50659/JPW/JM

HM31/0227

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EXAMINER	
EYLER, Y	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/813,323	Baltimore et al
Examiner	**Group Art Unit**
Yvonne Eyler	1806

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire [redacted] month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a CRAF polypeptide, classified in class 530, subclass 350.

II. Claims 5, 6, and 11-20, drawn to a method of inhibiting activation by CD40 ligand with a polypeptide, classified in class 514, subclass 2.

III. Claims 5-9 and 11-20, drawn to a gene therapy treatment to inhibit activation by CD40 ligand, classified in class 514, subclass 44.

IV. Claims 5 and 10-20, drawn to a method of inhibiting activation by CD40 ligand using a small molecule, classified in class 514, subclass 1.

2. The inventions are distinct, each from the other because of the following reasons: The inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I may be used in screening assays or to generate antibodies.

3. The inventions of Group I and Groups III and IV are entirely unrelated. The polypeptide of Group I is not necessary for the methods of Group III which uses nucleic acids or for the method of Group IV which uses a chemical.

4. The inventions of Groups II-IV are drawn to entirely different methods having different method steps and using different method compositions. Claims 5 and 11-20 are general claims

which do not specify the method of treatment and therefore have been placed in each of Groups II-IV. Should applicant elect one of Groups II-IV, claims 5 and 11-20 will be examined only in light of the elected invention. The methods Group II differs from that of Groups III and IV because it requires the administration of a protein which is not required by the latter two Groups. The method of Group III differs from Groups II and IV because it is drawn to gene therapy methods and requires the administration of nucleic acids and their expression which is not required in the practice of Groups II and IV. Group IV differs from Groups II and III in that it requires the use of a small molecule, presumably a chemical which is not required in the methods of either Groups II or III.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, because these inventions are distinct for the reasons given above and the search required for any single Group is not required for any of the other Groups, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. B-cells
b. T-cells
c. epithelial cells
d. fibroblasts
e. renal cells
f. smooth muscle cells.

The species of groups a-f are each drawn to a unique type of cell which is unrelated to the other types of cells and which have entirely different characteristics from each other. The different categories of cells are not related and each category would require a unique search not required for any other category. The search for B-cells would not provide information with regard to T-cells, epithelial cells, fibroblasts, renal cells or smooth muscle cells, for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5-12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**lila.feisee@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Yvonne Eyler, Ph.D.
February 24, 1998

Sheela Huff
SHEELA HUFF
PRIMARY EXAMINER